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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,529	07/07/2005	Bernd Fabry	C 2776 PCT/US	1490

23657 7590 02/13/2007  
COGNIS CORPORATION  
PATENT DEPARTMENT  
300 BROOKSIDE AVENUE  
AMBLER, PA 19002

EXAMINER
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CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,529	<b>Applicant(s)</b> FABRY, BERND	
	<b>Examiner</b> Catheryne Chen	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>Aug. 17, 2006, July 07, 2005</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Currently, Claims 11-29 are pending. Claims 1-10 are canceled.

#### ***Election/Restrictions***

Applicant's election with traverse of Claims 11-29 in the reply filed on Dec. 22, 2006 is acknowledged. Applicant elects the species *Trifolium pretense* and isoflavone glucosides. Claims 1-10 are canceled. Claims 11-29 are amended claims. The traversal is on the ground(s) that there is a common thread plant which connects all of the various species and genera into a single coherent group for chewing gum composition. This is not found persuasive because the plants are from different families; therefore, there is no common thread for the chewing gum composition. In addition, the plant-derived active principles do not share a common structure or are derived from a common structure. A search of one group is not coextensive with the search of the other groups. Thus, it would be burdensome to search the entire claims.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Objections***

Claims 16 and 22 are objected to because of the following informalities: There is an extra "d" after the word "and" for Claims 16 (b3) and 22 (b3). In Claim 16 (c2), the word aqueous is misspelled and there is a period after the word matrix. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Empie et al. (US 6261565 B1).

Applicant's claim is drawn to a chewing gum composition of water-insoluble base component, water-soluble component, *Trifolium pratense*, and isoflavone glycoside.

Empie et al. teaches isoflavone glycoside (column 1, lines 21), red clover (*Trifolium pratense*) (column 4, line 19), corn oil, sucrose (column 6, Table 1), orally administered as soft gels (column 7, lines 25, 31).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Empie et al. (US 6261565 B1) and Gurin (US 2002/0160077 A1).

Applicant's claim is drawn to a chewing gum composition of water-insoluble base component, water-soluble component, *Trifolium pratense*, and isoflavone glycoside.

Empie et al. teaches isoflavone glycoside (column 1, lines 21), red clover (*Trifolium pratense*) (column 4, line 19), orally administered as soft gels (column 7, lines 25, 31). However, it does not teach the other components or amounts.

Gurin teaches chewing gum (paragraph 0004), gum components from elastomers, plasticizers, fillers, softeners, waxes, antioxidants, colorants, emulsifiers, colors, acidulents, flavors, and colors (paragraph 0008), a water soluble gum portion and a water insoluble gum base portion (paragraph 0030), chitosan, polylactic polymers (paragraph 0052), proportion of water soluble component to oil soluble component distributed throughout the oil phase, causes the phases to become encapsulated, or by emulsifying the two phases by means of an emulsifying agent (paragraph 0044), cellulose fibers having particle size of not greater than 400 microns (paragraph 0069).

The reference also does not specifically teach combining *Trifolium pratense* and the claimed components together. The reference does teach that *Trifolium pratense* is orally administered as soft gels (see Empie et al., column 7, lines 25, 31). As discussed in MPEP 2144.06:

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

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used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, it would be obvious to combine *Trifolium pratense* with components to make a chewing gum for oral administration because they are taught in the reference to have the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 11-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over He et al. (US 6413546 B1) and Gurin (US 2002/0160077 A1).

Applicant's claim is drawn to a chewing gum composition of water-insoluble base component, water-soluble component, *Trifolium pratense*, and isoflavone glycoside.

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He et al. teaches disintegratable tablets containing isoflavone from red clover and soybean (column 1, lines 36-37; column 2, lines 5-7), isoflavone glucosides (column 7, line 34). However, it does not teaches the other components or amounts.

Gurin teaches chewing gum (paragraph 0004), gum components from elastomers, plasticizers, fillers, softeners, waxes, antioxidants, colorants, emulsifiers, colos, acidulents, flavors, and colors (paragraph 0008), a water soluble gum portion and a water insoluble gum base portion (paragraph 0030), chitosan, polylactic polymers (paragraph 0052), proportion of water soluble component to oil soluble component distributed throughout the oil phase, causes the phases to become encapsulated, or by emulsifying the two phases by means of an emulsifying agent (paragraph 0044), cellulose fibers having particle size of not greater than 400 microns (paragraph 0069).

The reference also does not specifically teach combining *Trifolium pratense* and the claimed components together. The reference does teach that *Trifolium pratense* is orally administered as tablets (see He et al., column 1, lines 36-37). As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine *Trifolium pratense* with components to make a chewing gum for oral administration because they are taught in the reference to have the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

### ***Conclusion***

No claim is allowed.

### ***Contact Information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
1-11-07  
SUSAN COE HOFFMAN  
PRIMARY EXAMINER

Catheryne Chen  
Patent Examiner  
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